

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P780PC00	FOR FURTHER ACTION <div style="text-align: right;">see Form PCT/ISA/220 as well as, where applicable, item 5 below.</div>	
International application No. PCT/DK2004/000375	International filing date (day/month/year) 28/05/2004	(Earliest) Priority Date (day/month/year) 30/05/2003
Applicant ALSENSA APS		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 9 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box II).

3. ☒ Unity of invention is lacking (see Box III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK2004/000375

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The present invention relates to a device (1) for delivering a medicament or a diagnostic agent to the skin or mucosa of an animal such as a human being, wherein a chamber (4) filled with the medicament or the diagnostic agent is separate from the housing (2) with a rod (29) capable of transferring the medicament or the diagnostic agent to the animal. The chamber (4) is connected to the housing (2) with the rod (29) before transfer of medicament or diagnostic agent. In particular the invention relates to a device (1) for delivering allergens in allergy tests.

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/103 A61B17/20 A61M37/00 A61M5/50

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B A61D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 202 14 019 U (ROESCH AG MEDIZINTECHNIK) 16 January 2003 (2003-01-16) page 1, line 12 - line 21 page 9, line 7 - line 22 figure 1	1, 2, 8, 32-34
Y	----- -/--	35

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

8 December 2004

Date of mailing of the international search report

17/12/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Sedy, R

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/34739 A (MOELLSOEE CLAUS ;ROENBORG STEEN MEIER (DK)) 15 July 1999 (1999-07-15) page 5, line 37 - page 6, line 11 page 7, line 28 - page 9, line 2 page 10, line 17 - line 20 page 11, line 15 - line 19 page 12, line 12 - line 17 figures 1-6	32-34
Y A		27-29 1,2,4-9, 13-20
X	US 5 441 490 A (SVEDMAN PAL) 15 August 1995 (1995-08-15) abstract; figures 21-24	32
A		1,2
X	WO 00/02605 A (NOVONORDISK AS) 20 January 2000 (2000-01-20) page 7, line 27 - line 29 page 8, line 5 - line 13 figures	34
Y A		29 1
Y	DE 37 37 570 A (SBC SL) 3 November 1988 (1988-11-03) column 1, line 45 - line 51; figure 1	27,28,35
A	EP 0 460 327 A (MIYARISAN KABUSHIKI KAISHA) 11 December 1991 (1991-12-11). figure 1	21,32
A	US 5 104 375 A (WOLF STEPHEN J ET AL) 14 April 1992 (1992-04-14) column 3, line 48 - line 50 figures 1,5	22-26
A	US 4 392 859 A (DENT HUGH R) 12 July 1983 (1983-07-12) column 3, line 16 - line 35 figure 1	32
A	US 4 482 348 A (DENT HUGH R) 13 November 1984 (1984-11-13) column 4, line 52 - line 57 figure 3	1,32,34
A	EP 0 182 682 A (REVEILLON JEAN ANDRE HENRI) 28 May 1986 (1986-05-28) page 9, line 2 - line 6 page 9, line 12 - line 14 figures 1-3	1,32,34

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 30,31

Claims 30,31:Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2004/000375

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 30, 31
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 30,31: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE 20214019	U	16-01-2003	DE 10211473 A1	16-10-2003
			DE 20214019 U1	16-01-2003
WO 9934739	A	15-07-1999	AT 269669 T	15-07-2004
			AU 736958 B2	09-08-2001
			AU 1869999 A	26-07-1999
			DE 69918266 D1	29-07-2004
			WO 9934739 A1	15-07-1999
			EP 1047343 A1	02-11-2000
			JP 2002500061 T	08-01-2002
			NO 20003441 A	03-07-2000
			US 6447482 B1	10-09-2002
US 5441490	A	15-08-1995	AU 662000 B2	17-08-1995
			CA 2100166 A1	10-07-1992
			DE 69208458 D1	28-03-1996
			DE 69208458 T2	08-08-1996
			EP 0566605 A1	27-10-1993
			GR 3019676 T3	31-07-1996
			JP 3236021 B2	04-12-2001
			JP 6504215 T	19-05-1994
			US 2002115967 A1	22-08-2002
			US 6048337 A	11-04-2000
			US 2004236248 A1	25-11-2004
			AT 134311 T	15-03-1996
			AT 197677 T	15-12-2000
			AU 1984092 A	17-08-1992
			AU 670733 B2	25-07-1996
			AU 2009695 A	27-07-1995
			DE 69231577 D1	28-12-2000
			DE 69231577 T2	29-03-2001
			DK 566605 T3	08-07-1996
			WO 9211879 A1	23-07-1992
			EP 0680766 A2	08-11-1995
			ES 2086114 T3	16-06-1996
			ES 2153454 T3	01-03-2001
			GR 3035419 T3	31-05-2001
WO 0002605	A	20-01-2000	AT 251477 T	15-10-2003
			AU 4769599 A	01-02-2000
			BR 9911933 A	27-03-2001
			CA 2336758 A1	20-01-2000
			CN 1308550 T	15-08-2001
			DE 69911965 D1	13-11-2003
			DE 69911965 T2	12-08-2004
			WO 0002605 A1	20-01-2000
			EP 1094857 A1	02-05-2001
			HU 0102525 A2	28-11-2001
			JP 2002520097 T	09-07-2002
			NO 20010092 A	06-03-2001
			PL 345336 A1	17-12-2001
			US 6562011 B1	13-05-2003
			ZA 200100182 A	23-08-2001
DE 3737570	A	03-11-1988	ES 2004405 A6	01-01-1989
			DE 3737570 A1	03-11-1988
EP 0460327	A	11-12-1991	JP 4030534 U	11-03-1992

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0460327 A		JP 7013714 Y2	05-04-1995
		JP 4030535 U	11-03-1992
		JP 7013715 Y2	05-04-1995
		DE 69009045 D1	23-06-1994
		DE 69009045 T2	06-10-1994
		EP 0460327 A1	11-12-1991
US 5104375 A	14-04-1992	US 4979942 A	25-12-1990
		AT 106781 T	15-06-1994
		AU 631686 B2	03-12-1992
		AU 6453790 A	18-04-1991
		BR 9005149 A	17-09-1991
		CA 2027672 A1	17-04-1991
		EP 0424068 A2	24-04-1991
		ES 2055340 T3	16-08-1994
		IE 903689 A1	24-04-1991
		JP 3004342 B2	31-01-2000
		JP 3184561 A	12-08-1991
		NZ 235492 A	26-05-1993
		ZA 9008236 A	24-06-1992
US 4392859 A	12-07-1983	AR 227554 A1	15-11-1982
		AU 547355 B2	17-10-1985
		AU 7349981 A	23-09-1982
		AU 545555 B2	18-07-1985
		AU 7350081 A	23-09-1982
		BE 889770 A1	16-11-1981
		BR 8104873 A	13-04-1982
		CA 1162800 A1	28-02-1984
		CH 644022 A5	13-07-1984
		DE 3129624 A1	09-06-1982
		DK 336381 A	30-01-1982
		EP 0045616 A1	10-02-1982
		ES 8301639 A1	01-04-1983
		FR 2487678 A1	05-02-1982
		GB 2080688 A ,B	10-02-1982
		GB 2080689 A ,B	10-02-1982
		IE 51837 B1	15-04-1987
		IL 63448 A	30-06-1985
		IN 154961 A1	22-12-1984
		IN 155453 A1	02-02-1985
		IT 1138878 B	17-09-1986
		JP 57057558 A	06-04-1982
		JP 57052462 A	27-03-1982
		NL 8103581 A ,B,	16-02-1982
		NZ 197866 A	28-02-1985
		NZ 197867 A	19-10-1984
		SE 445175 B	09-06-1986
		SE 8104573 A	30-01-1982
		US 4507118 A	26-03-1985
		ZA 8105171 A	25-08-1982
		ZA 8105172 A	25-08-1982
US 4482348 A	13-11-1984	AU 553605 B2	24-07-1986
		AU 1034083 A	21-07-1983
		DE 3317675 A1	15-11-1984
		GB 2114006 A ,B	17-08-1983
		NZ 203018 A	09-05-1986

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4482348	A	ZA 8300218 A	30-11-1983
EP 0182682	A	28-05-1986	
		FR 2571972 A1	25-04-1986
		FR 2580179 A2	17-10-1986
		EP 0182682 A1	28-05-1986

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/DK2004/000375

International filing date (day/month/year)
28.05.2004

Priority date (day/month/year)
30.05.2003

International Patent Classification (IPC) or both national classification and IPC
A61B5/103, A61B17/20, A61M37/00, A61M5/50

Applicant
ALSENSA APS

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Sedy, R

Telephone No. +31 70 340-2978



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

10/558943

International application No.
PCT/DK2004/000375

AP16 Rec'd PCT/PTO 30 NOV 2005

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 30,31

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 30,31

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-29,32,33,34,35,36

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3-29,33,35,36
	No: Claims	1,2,32,34
Inventive step (IS)	Yes: Claims	
	No: Claims	1-29,32-36
Industrial applicability (IA)	Yes: Claims	1-29,32-36
	No: Claims	

2. Citations and explanations

see separate sheet

IAP16 Rec'd 03/11/2005 30 NOV 2005

The following documents are referred to in this communication.

- D1 : DE 202 14 019 U (ROESCH AG MEDIZINTECHNIK) 16 January 2003
(2003-01-16)
- D2 : WO 99/34739 A (MOELLSOEE CLAUS ;ROENBORG STEEN MEIER (DK))
15 July 1999 (1999-07-15)
- D3: US-A-5 441 490 (SVEDMAN PAL) 15 August 1995 (1995-08-15)
- D4: DE 37 37 570 A (SBC SL) 3 November 1988 (1988-11-03)
- D1: EP-A-0 460 327 (MIYARISAN KABUSHIKI KAISHA) 11 December
1991 (1991-12-11)
- D5: EP-A-0 460 327 (MIYARISAN KABUSHIKI KAISHA) 11 December 1991
(1991-12-11)
- D6: US-A-5 104 375 (WOLF STEPHEN J ET AL) 14 April 1992 (1992-04-14)

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No opinion has been established regarding claims 30 and 31 since their subject-matter refers to a method for treatment of the animal body by therapy, namely (see page 23, line 21,22) "delivering said medicament ... to said animal." Consequently, claims 30 and 31 concern a medical method which is excluded from international preliminary examination (Article 34(4)a, Rule 67(1)(iv) PCT).

Re Item IV

Lack of unity of invention

- 1 The application comprises two groups of claims:
 - 1.1 Group I: Claims 1-26, 29, 32-34 are related to a delivery device comprising specific configurations of a rod and a chamber house having a chamber with first and second sealings and an axis intersecting both sealings (purpose: ease of use of a rod and secure storing of a medicament).
 - 1.2 Group II: Claims 35, 36, 27, 28 are related to a device for delivering a medicament comprising labelling means (purpose: avoiding of multiple injection to the same animal).

The features common to claims 1 and 35 are disclosed in D1, see item V below. Consequently, these common features cannot constitute the special technical features referred to in Rule 13.2 PCT, second sentence.

Since in both independent claims of the above listed groups of claims no other common or corresponding technical features (the problems to be solved are different) exist, which can be considered as special technical features within Rule 13.2 PCT, second sentence, no technical relationship within the meaning of Rule 13.1 PCT between the different subjects as above can be seen.

Without a technical relationship the subjects are not so linked as to form a single inventive concept. As such the requirement of unity of invention according to Rule 13.1 PCT is not fulfilled.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 First subject-matter: **claims 1-26, 29, 32-34**

1.1 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (see e.g. page 9, lines 7-22, Figure 1)

- a) a device for delivering a medicament or a diagnostic agent to the skin or mucosa of an animal, the device having
- b) at least one rod house (1) and at least one separate chamber house (2), wherein the chamber house (2) is capable of being connected to the rod house (1) (which is possible by the threads (15,16)),
- c) wherein the rod house (1) having at least one housing, the at least one housing having a distal end (the end including Gewinde (16)) and a proximal end, and at least one rod (5,7), the rod having a distal end (5) and at least one proximal end (7), and the rod being slidably arranged in the housing (1), the rod (5,7) being capable of being activated by being pushed towards the proximal end of the housing (1), and
- d) a chamber house (2) having a chamber (12), a first wall of the chamber (12) being

a first sealing (11) and a second wall of the chamber (12) being a second sealing (10), the first sealing (11) and the second sealing (10) being arranged so that an axis through the chamber (12) may intersect both sealings (10,11), and the chamber (12) having the medicament or the diagnostic agent.

1.2 Consequently, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

1.3 Dependent **claims 2-26, 29** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see for example:

1.3.2 novelty

D1, page 9, lines 7-22, for **claim 2**;

1.3.3 inventive step

D2, see passages cited in the search report, for **claims 4-9 and 13-20**;

D5, see figure 1, for **claim 21**;

D6, see column 3, lines 48-50, figures 1 and 5, for **claims 22-26**;

Claim 8: D1 discloses "Auslöser 6" which, when in the position as represented in Figure 1, would clearly mark that the rod has been activated;

Claims 3,10-12 define features which present several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill.

Claim 29: The chamber disclosed in D1 is clearly intended to be filled with medicament or diagnostic agent.

2.1 INDEPENDENT CLAIM 32

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 32 is not new in the sense of Article 33(2) PCT.

See document D1, page 9, lines 7-22, Figure 1 and the features as already listed in above paragraph 1.1 d).

Moreover, in addition to D1, also D2 and D3 (see passages referred to in the search report) present prior art documents which clearly disclose a chamber house such as defined in claim 32.

2.2 The subject-matter of dependent **claim 33** does not comply with the requirements of the PCT regarding inventive step since the chamber disclosed in D1 is not limited to a particular medicament and, consequently, could also be filled with an allergen or a combination of allergens which, as such, are already well known in the medical field.

3.1 INDEPENDENT CLAIM 34

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 34 is not new in the sense of Article 33(2) PCT.

See document D1, page 9, lines 7-22, Figure 1 and the features as already listed in above paragraph 1.1 c).

4. Second subject-matter: **claims 35,36,27,28**

4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 35** does not involve an inventive step in the sense of Article 33(3) PCT.

The delivery device as specified in claim 35 differs from the one as specified in claim 1 only in that the chamber house is provided with a labelling means.

The labelling means is also the only subject-matter not already anticipated by D1.

The problem to be solved by the present invention may therefore be regarded as avoiding of multiple injection to the same animal.

The solution proposed in claim 35 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) since such a labelling means is already described in document D4 (see column 1, lines 45-51, Figure 1) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the delivery device described in document D1 in order to solve the problem posed.

4.2 For the subject-matter of claim 36, see above paragraph 1.3.

4.3 Dependent **claims 27, 28** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see for example: D4, column 1, lines 45-51, Figure 1.

Re Item VIII

Certain observations on the international application

- 1.1 The subject matter of Claim 34 does not fulfill the requirements of Article 6 PCT since it is not clear. In particular, it is not clear how a rod house can be connected to a chamber house according to claim 1 which comprises already a rod house. Consequently, claim 34 can only be related to claim 32 defining a chamber house.
- 1.2 The subject matter of Claim 32 does not fulfill the requirements of Article 6 PCT since it is not clear. In particular, it is not clear how a chamber house can be *made suitable* for being connected to a rod house according to claim 1 which comprises already a chamber house. Consequently, claim 32 can only be related to claim 34 defining a rod house.
- 2.1 Claims 6 is unclear, contrary to the requirements of Article 6 PCT, because of its inconsistent reference to "any of the preceding claims" although "the needle", as defined in it, can only be made dependent on claim 5.
- 2.2 Claims 9-12 can only be made dependent on claim 8 due to "marking means" as defined in this claim (Article 6 PCT).
- 2.3 Claim 14 can only be made dependent on claim 13 due "means for retracing the rod" (Article 6 PCT).
- 3 Claims 15 and 16: "the housing" should probably read "the rod housing".
- 4 Figure 10 comprises surfaces with different shades of grey which does not comply with the requirements of Rule 11.13. PCT.